FEB 17 2012

III. 510(k) Summary

BaroSense ACE™ Stapler and Cartridge

BAROSENSE INC

General Information

Criteria	*Information*
Trade Name	ACE™ Stapler and Cartridge
Product Name	ACE Stapler and Cartridge
Catalog/Model Number	BRH-01 ACE Stapler Reusable Handle BH8-01 ACE Stapler Head and Accessories BC8-01 ACE Stapler Cartridge
Common Name	surgical stapler and cartridge
Classification	21 CFR 876.1500- Endoscope and Accessories; Class II; Product code: OCW
510(k) Owner	BaroSense, Inc. 250 Chesapeake Drive Redwood City CA 94063
Contact Person	Sheila Stevens, PhD Director Clinical and Regulatory Affairs BaroSense, Inc. sstevens@barosense.com 650-362-6016 (phone) 650-362-0070 (fax)

Summary of Substantial Equivalence

The BaroSense, Inc., ACE Stapler and Cartridge (component models BRH-01, BH8-01 and BC8-01) are substantially equivalent to the BaroSense ACE Stapler and Cartridge (component models F0084, F0085 and F0086).

Date: January 17, 2012

Predicate Devices

Manufacturer	*Predicate device*	*510(k)*
BaroSense, Inc. Redwood City, CA	F0084 ACE Stapler Reusable Handle F0085 ACE Stapler Head F0086 ACE Stapler Cartridge	K110829

Device Description

The ACE™ Stapler is a surgical stapler used in hospitals or surgery centers for staple closure on the wall of the stomach or gastrointestinal tract.

The single-patient-use, disposable stapler head is supplied non-sterile and is fitted with a sterile, single-use staple cartridge. The stapler head is attached to a reusable, flexible stapler handle that controls the position and articulation of the stapler head. In use, the stapler is introduced into the patient through the mouth. A flexible endoscope passes through the stapler for gastric tissue visualization. The stapler works in conjunction with a vacuum pump to create a plication (tissue fold) in the GI tract, which is then compressed. The stapler then places a double ring of titanium staples (8 staples). A non-absorbable ring helps reinforce the staple placement in the tissue. The tissue compression and stapling functions are controlled by commercially available inflation syringes.

An endogastric overtube may be used to protect the esophageal tissues during repeated insertions of the device. The overtube, flexible endoscope, vacuum pump and inflation syringes used with the stapler are all commercially available medical devices, not the subject of this 510(k), and are not supplied with the stapler.

The predicate device has identical technological characteristics as the modified device. However, the predicate stapler device delivers a double ring of 10 staples, rather than 8. The change in staple pattern and other minor changes to the stapler head allow a smaller overall stapler head diameter compared to the predicate. The modified stapler handle also has a slightly smaller diameter and a longer articulation section than the predicate device.

Indications for Use

The BaroSense ACE Stapler is indicated for endoluminal trans-oral tissue approximation and ligation in the gastrointestinal tract.

Bench/Animal Testing

All patient-contacting components of the ACE Stapler are composed of materials of known biocompatibility and tested to the requirements of ISO 10993 for the predicate device. The only new material for the modified device is a white orientation marking on the flexible portion of the stapler handle. The new material has also been tested to the requirements of ISO 10993. The safety and effectiveness of the device was further established through a series of bench and animal tests. All testing yielded acceptable results.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Sheila Stevens, Ph.D.
Director, Clinical and Regulatory Affairs
BaroSense, Inc.
250 Chesapeake Drive
REDWOOD CITY CA 94063

FEB 17 2012

Re: K120147
Trade/Device Name: ACE™ Stapler and Cartridge
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: OCW
Dated: January 17, 2012
Received: January 18, 2012

Dear Dr. Stevens:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

II. Statement of Indications for Use

510(k) Number (if known): K120147

Device Name: ACE™ Stapler and Cartridge

Indications for Use: The BaroSense ACE Stapler and Cartridge are indicated for endoluminal trans-oral tissue approximation and ligation in the gastrointestinal tract.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

Concurrence of CDRH, Office of Device Evaluation (ODE)

2/17/2012

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K120147

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